

11556-14

12/3/2013

1/10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. J. Todd Frank
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

DEC - 3 2013

Subject: Label Notification(s) for Pesticide Registration Notice 98-10.

Dear Mr. Frank:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 November 21, 2013 for the following product(s):

CO-Ral® Animal Insecticide EPA Reg. No. 11556-14
1% Bulk Dust

The Registration Division (RD) has conducted a review of this request for applicability under PR Notice 98-10 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please contact Linda A. DeLuise at 703-305-5428.

Sincerely,

A handwritten signature in cursive script that reads "Linda A. DeLuise".

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Please read instructions on reverse before completing form.

Form Approved.

No. 2070-0080



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-14	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CO-RAL (Coumaphos) Animal Insecticide 1% Bulk Dust	PM# Team Number 10	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar to a previously registered pesticide in its composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. <u>DEC - 3 2013</u> Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Minor Formulation Amendment per PR Notice 98-10. See attached Explanation page.
E-mail Contact: todd.frank@bayer.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name J. Todd Frank	Title Reg. Affairs Consultant	Telephone No. (Include Area Code) 913-268-2585
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Consultant	
4. Typed Name J. Todd Frank	5. Date 11/21/2013	



Bayer HealthCare

November 21, 2013

Document Processing Desk (**NOTIF**)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Richard Gebken, Team 10

Subject: **CO-RAL (Coumaphos) Animal Insecticide 1% Bulk Dust**
EPA Reg. No. 11556-14
Application for Notification

Dear Mr. Gebken,

Please find the enclosed Pesticide Notification application for subject product which includes one highlighted label copy and ~~two~~ ^{one} un-highlighted label copies.

As allowed by PR Notice 98-10, Bayer HealthCare LLC Animal Health Division is adding an alternate package size and additional optional labeling. The alternate package size will include two fully labeled 12.5 pound containers of bulk dust as well as an application bag. Full labeling will be on the new outer package identical to the individual packages with the optional text stating that an application bag is included.

Thank you for your assistance with this notification process, and please contact me at (913) 268-2585 or todd.frank@bayer.com if you have any questions or need further information.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Regards,

BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION

J. Todd Frank
Regulatory Affairs Consultant

Bayer HealthCare LLC
Animal Health
P.O. Box 390
Shawnee Mission, KS
66201-0390

4110

Reason to Issue: Add additional optional text.

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Co-Ral® Animal Insecticide

1% Bulk Dust

NOTIFICATION

DEC - 3 2013

Control of Horn Flies and Lice on Beef and Dairy Cattle, Reduction of Face Flies on Beef and Dairy Cattle, Control of Lice on Swine

[Alternate Brand Name: Co-Ral 1% Livestock Dust]

Use in Dust Bag or Shaker Can

Optional text in brackets [Contains:]
[Contains refillable dispenser bag]
[Two 12.5 lb. bags of dust]

	Percent by Weight
Active Ingredient:	
coumaphos.	1%
Other Ingredients	99%
TOTAL.	100%

EPA Reg. No. 11556-14

EPA Est. No. TBD

Keep Out of Reach of Children

CAUTION

Harmful if swallowed, absorbed through the skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, and clothing.

See Side Panel for First Aid and Other Precautionary Statements

NET CONTENTS: [12.5 POUNDS]; [2 Pounds]; [Two 12.5 Pounds]

Manufactured for
Bayer HealthCare LLC, Animal Health Division
PO Box 390
Shawnee Mission, Kansas 66201

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

FIRST AID	
Contains an organophosphate that inhibits cholinesterase.	
If swallowed:	<ul style="list-style-type: none"> • Call poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If inhaled:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
Note To Physician: Prolonged exposure will result in cholinesterase depression. Atropine sulfate by injection is antidotal. 2-PAM is also antidotal and may be administered in conjunction with atropine.	
HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment call 1-800-422-9874. For customer service or to obtain product information, including the MSDS, call 1-800-633-3796.	

CAUTION

PERSONAL PROTECTIVE EQUIPMENT

Some materials that are chemical-resistant to this product are rubber or waterproof material. If you want more options, follow the instructions for Category A on an EPA chemical-resistance category selection chart.

Loaders, applicators and others handlers must wear long-sleeve shirt and long pants, chemical-resistant gloves, shoes plus socks, chemical-resistant apron, and a NIOSH-approved dust/mist respirator, with MSHA/NIOSH approval number prefix TC21C or a NIOSH-approved respirator with any N, R, P, or HE filter.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from the other laundry.

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to mammals, birds, fish and aquatic invertebrates. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label and Conditions of Sale before using this product.

Co-Ral 1% Bulk Dust [Alternate Brand Name] may be used to fill cattle dust bags or it may be applied directly to cattle, swine or swine bedding by use of a shaker can. When used as recommended, Co-Ral 1% Dust [Alternate Brand Name] controls horn flies and lice on beef and dairy cattle and lice on swine. Co-Ral 1% Dust [Alternate Brand Name] will also reduce face fly populations on cattle; however, as face flies are able to travel over an area of several miles, best reduction of face fly populations is achieved when Co-Ral 1% Dust [Alternate Brand Name] is used on an area-wide basis.

APPLICATION RESTRICTIONS

The use of mechanical dusters is prohibited.

For external insecticidal use only on specified animals. Do not contaminate feed, troughs, water or water utensils. Provide thorough ventilation while dusting. Do not apply to sick, stressed or convalescent animals.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Individuals must limit the number of animals they can treat per day with shaker can to no more than 25 and the area of swine bedding they can treat per day to 1,000 sq. ft.

Do not treat areas such as drinking cups, mangers, or troughs where livestock feed. Do not contaminate food, feedstuffs, food or feed handling equipment or milk or meat handling equipment.

Entry restrictions: Do not enter treated areas or allow contact with treated animals until dusts have settled.

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INSTALLATION OF DUST BAGS:

Suspend the bags by inserting rope, chain or wire through the grommets at the top of the bag and attaching to an overhead structure or by hooking the grommets into hooks fastened to a stationary overhead 2 x 4 board at the heights recommended for louse and horn fly or face fly control. In areas of frequent or heavy rainfall Co-Ral 1% Cattle Duster should be protected from the weather.

Install as many Co-Ral 1% Cattle Dusters as necessary to lanes or other openings to assure proper dusting of the animals. After the bags are in place, pull the rip cord to allow the insecticide to fall into the bottom of the bag. When dust bags are provided on a free-choice basis, allow one 12.5-pound Co-Ral 1% Duster per 25 animals.

APPLICATION RATES

ANIMAL	PARASITE	REMARKS
Beef and Dairy Cattle	Horn Flies Lice Face Flies	<u>DUST BAG:</u> Place contents of this package in any commercially available dust bag. Suspend bags in areas frequented by cattle or in gateways or lanes through which the animals pass daily for water, feed or minerals. Bags may also be suspended in loafing sheds or in front of protected mineral feeders. For lactating dairy cows bags may be suspended in the exit through which cows <u>leave</u> the milking barn. In all cases the bags should be adjusted so that the bottom of the bag will hang four to six inches below the topline of the cattle. <u>For reduction of face flies:</u> (1) The bottom of the bags should be 18 to 24 inches from the ground to insure that the faces of the cattle will be dusted. (2) The bags must be located so the animals will be forced to use them daily.
	Horn Flies Lice	<u>DIRECT APPLICATION:</u> Co-Ral 1% Dust [Alternate Brand Name] may be applied by use of a shaker can. Animals should be thoroughly dusted using not more than 2 oz.* (6 level tablespoonfuls) of dust per animal per treatment. Treat no more than 12 times per year. Do not make applications less than 10 days apart.

(Continued)

APPLICATION RATES

ANIMAL	PARASITE	REMARKS
Swine	Lice	<p><u>DIRECT APPLICATION</u>: Apply not more than 1 oz.* (3 level tablespoonfuls) per head as a uniform coat to the head, shoulders and back by use of a shaker can. Treat no more than 6 times per year. Do not make applications less than 10 days apart.</p> <p><u>BEDDING TREATMENT</u>: Apply 2 oz.* (6 level tablespoonfuls) uniformly over 30 square feet of fresh, dry bedding by use of shaker can. Treat no more than 6 times per year. Do not make applications less than 10 days apart.</p> <p><u>DIRECT APPLICATION AND BEDDING TREATMENT</u>: In severe infestations both individual animals and the bedding may be treated as directed above.</p>
No interval is required between treatment and slaughter or between treatment and use of milk as feed.		

*Note: 1 oz of this material equals approximately three level tablespoonfuls.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry place.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Completely empty the container by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Offer for recycling, if available. Dispose of bags in a sanitary landfill or by incineration if allowed by state and local authorities.

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Conditions of Sale: The directions on this label are believed to be adequate and must be followed carefully. This product has been tested under different environmental conditions similar to those that are ordinary and customary for use of the product. However, it is impossible to eliminate all risks associated with the use of this product. Failure to follow label directions may cause injury to animals, humans and damage to the environment. Insufficient control of pests, injury or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer HealthCare LLC. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

Limited Warranty and Limitation of Damages: Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL, and no agent of Bayer is authorized to make or modify any warranties beyond those contained herein. Any damages arising from breach of this warranty shall be limited to direct damages and shall not include special, incidental or consequential damages resulting from the use of handling of this product.